

PLEASE notify the DPHL <u>prior</u> to collecting a sample to discuss specimen/sample type, to confirm testing methods available, and to coordinate transportation. This document is for non-routine samples. Utilize the latest version of the Specimen Collection Protocol to determine the specimen collection and storage criteria prior to testing.

ALL PREPAREDNESS, SDWA, AND POTENTIAL LEGAL SAMPLES:

- 1. DPHL requires prior authorization for receipt of any non-routine sample or specimen to our facility for testing. Contact the Laboratory Director or designee at (302) 223-1520 PRIOR to submission. Samples arriving at DPHL without authorization will be rejected and not tested. Routine samples are assumed to have received prior authorization. If in doubt, contact DPHL.
- 2. DPHL requires the specific documentation to be completed for submission of non-routine samples for testing at DPHL.
- 3. Documentation required is based on the type and purpose of sample being submitted.
- 4. <u>Clinical specimens</u> are directly from a living entity (i.e., blood, urine, fecal matter, fluids, organs, or derivatives, etc.). They are collected in a medical (hospital, clinic, field) setting by medical personnel. Collection maybe initiated in a variety initiated points, such as a hospital emergency department, laboratory, field response, etc. Clinical specimens require the following documentation:
 - a. Chain of Custody
 - b. Request for Preparedness Testing
 - c. LIMS Test Requisition
- 5. Environmental Specimens are non-clinical derived samples. This is the largest and most diverse category of samples and can include solids, liquids, powders, mixed phases, soil, etc. Environmental samples do not include routine compliance sample for SDWA. These samples could be collected by law enforcement (FBI), emergency personnel, HazMat (DNREC) teams, etc. Environmental samples require the following documentation:
 - a. Chain of Custody
 - b. Request for Preparedness Testing
 - c. Field Screening Form
- 6. <u>Food Specimens</u> are derived or actual food material (i.e., food stocks, pre and post-processing, derivative materials, etc.). They are collected by a variety of personnel, including emergency response, Public Health, considered "non-clinical". Food specimens require the following documentation:
 - a. Chain of Custody
 - b. Request for Preparedness Testing
 - c. Field Screening Form
- 7. <u>SDWA Specimens</u> are samples collected for compliance or emergency samples for SDWA testing. These include public, private, or miscellaneous samples collected by authorized and trained collectors for SDWA analysis. These exclude potential contamination or intentional introduction of contaminants into a system to introduce potential harm (i.e., preparedness type samples). SDWA specimens require the following documentation:
 - a. Chain of Custody



- b. SDWA/ODW Test Requisition (Bacteriological Form or Chemical Form) if not entered into LIMS
- 8. Other/Isolate Specimens do not meet any of the other definitions and include rule-out isolates from clinical samples. Other specimens require the following documentation:
 - a. Request for Preparedness Testing (other)
 - b. LIMS Test Requisition (isolates)
 - c. Additional documentation as requested

Chain of Custody: Each person who accepts custody of a legal sample also accepts responsibility for ensuring the security of that sample. A sample is considered under custody if it is in your possession, in your view after being in your possession, or placed in a secure area (i.e., sealed container for shipping or an area accessible by authorized personnel only) after being in your possession. If a legal sample is to be left unattended, it should always be stored in a locked compartment. When possible the sample transport container should also be locked or sealed (i.e. evidence tape or other custody seal) in a manner to detect tampering.

- 1. The COC establishes an intact, contiguous record of the physical possession including collected samples, sample aliquots, and sample extracts, or digestates.
 - a. Detail the number of sample containers. (Count each of the 3 vials submitted for a single VOA sample, i.e. 1 sample = 3 containers)
 - b. Use a unique identification code (preferably LIMS barcode stickers) for each sample and container. If LIMS barcodes are not available, use the two-digit year followed by the two-digit month then two-digit date followed by an incrementing two-digit number Add an alpha character to differentiate collection sites. (i.e., 071201-3A would be the third sample collected on 01 December 2007 at the first site).
 - c. DPHL staff will assign a unique LIMS identification code upon receipt of the specimen at DPHL.
- 2. Record the printed name and signatures of all individuals who are actively involved with physically handling the samples on the COC form. Include all receivers and relinquishers (transferors and transferees).
 - a. In order to simplify record keeping, the number of people who physically handle the sample should be minimized.
- 3. The COC records shall account for all time periods associated with the sample.
 - a. If samples are stored in the field prior to delivery to the laboratory, detail the location, storage conditions (i.e., chemical or thermal preservation), and security condition (i.e., locked or sealed cooler) of those samples on the COC form.
 - b. Detail sample destruction or disposal on the COC form.
- 4. Seal transport containers with a tamper-proof custody seal and a strapping or sealant tape.
 - a. The custody seal must have space for the signature of the person who affixed the seal along with the date and time.
 - b. Place the seal so that the transport container cannot be opened without breaking the seal.
 - c. Record the time, calendar date, and signatures of responsible personnel affixing and breaking all seals shall on the COC form.



- d. When sample containers are shipped by a common carrier, include all common carrier and/or shipping documentation. These documents must be completed and retained with the sample file.
- 5. Shipping bills (i.e., Federal Express, UPS, etc.) will be retained with the COC or field sheet. Local samples are transported to the lab by DNREC personnel or other authorized personnel. The DPHL courier may be utilized to transport clinical specimens.
- 6. Make all record entries with waterproof ink. Do not obliterate entries by erasures or markings in records. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction must sign (or initial) and date the correction.
- 7. Utilize a waterproof, sealable bag or zipper bag to maintain all records in a manner that facilitates documentation tracking and allows historical reconstruction of all analytical events and ancillary procedures that produced the resultant sample analytical data.
- 8. The collector initiates the Chain of Custody. Complete each section in detail.
 - <u>Barcode Number</u>: list unique identifier or barcode assigned. Each sample requires its own unique ID
 - <u>Sample Date</u>: date sample collected
 - <u>Sample Time</u>: time sample collected. It is recommended that all time be recorded using 24-hour notation (e.g., 2:00 PM is 1400 hours).
 - <u>Water System Name/Submitter</u>: individual submitting sample for analysis OR water system submitting samples (SDWA only)
 - <u>Comments</u>: self-explanatory
 - <u>Sample description</u>: brief description of sample to allow differentiation of this sample from any other
 - <u>Number of Containers for one Sample Slip</u>: how many samples for each type shown submitted per unique identifier
 - a. Columns denote type of container submitted
 - b. Pre-filled columns for SDWA samples
 - c. Preservative, container type, volume, # containers required
 - d. Non-SDWA samples use Clinical or Other column
 - e. Complete preservative (SDWA only), container type, container volume, and # of containers
- Blanks: container blanks provided, include number in each column
- Total Number of Containers: cumulative total of containers in that column, include blanks
- <u>Special Requests</u>: any notes regarding variation or change in protocol or testing requirements. This area can also include corrections or amendments to the CoC (i.e., incorrect date, etc.).
- 9. Signature block
 - a. Record of sample collection, transfer, and disposition
 - b. Record each individual receiving and possessing custody
 - c. Complete the whole line
 - d. Initial custody begins with sample collector on the "Sampled By" line
 - e. No blank lines between custody transfers



- 10. The signature block contains a horizontal sequence that details the transfer. It includes:
 - a. Printed name for each transferor
 - b. Signature for each transferor
 - c. Date of each transfer
 - d. Time of each transfer
 - e. Temperature of provided temperature control (for SDWA and CT samples)
 - f. Seal verification area
- 11. For each transfer, include:
 - a. Individual possessing custody records information at "Relinquished By"
 - b. Individual receiving custody records information at "Received By" line immediately below relinquisher
 - c. Completely fill in each line; do not leave blank, note "N/A" if the area is non-applicable (i.e., temperature control for food specimen).
- Sampled by: the initial sample collector must complete this horizontal line
- Received by: each person who receives the samples from the current custody holder
- Relinquished by: current custody holder transferring samples and custody to next individual
- <u>Page of</u>: enter page number and total number of pages
- <u>Temp CTL (°C)</u>: enter temperature of the temperature control in degrees Celsius; SDWA and Chemical Terrorism samples require temperature controls. All other samples enter "N/A"
- Sealed $(\sqrt{})$: verify the evidentiary seal is intact; if it is intact place a check $(\sqrt{})$ in the box. If it is not intact, write "failed" or similar notation. Preparedness samples require intact evidentiary seals. SDWA samples enter "N/A".

Request for Preparedness Testing: A Request for Preparedness Testing must be completed for each sample batch submitted for testing and must accompany the Chain of Custody Form. This document details the incident and/or specimen sampling site and address, the requested analyses, testing requested, and submitter information.

- 1. Complete ONE Request per batch of samples submitted.
- <u>Original Specimen Collected by</u>: Include the printed name and signature of personnel collecting samples / specimens.
- Collection Date: Note the collection date, including four-digit year.
- <u>Collection Time</u>: Note the time of sample collection It is recommended that all time be recorded using 24-hour notation (e.g., 2:00 PM is 1400 hours).
- <u>Collection Location</u>: Note the area of collection in reference to the physical address.
 - a. i.e., 1st floor bathroom, conference room table, 3rd row of corn field, etc.
- <u>Collection Conditions</u>: Note the temperature and conditions as these may affect stability and testing.
 - a. i.e., dry surface (desk), 78°F, inside building
 - b. i.e., wet pavement, 5°F, blowing snow, overcast
- <u>Incident Description</u>: list what occurred, observed, or speculated, impact or how sample came about in reference to an incident, exposure, or event.



- <u>Incident Address</u>: list the physical address of incident (if known)
- <u>Signs and Symptoms, Onset, Diagnosis</u>: if present, what signs and symptoms, the onset and severity, how many affected (all, some, one), if any diagnostic inference is made. If none, mark N/A or none.
- <u>Level of Risk</u>: High, Moderate, Low, or Exercise. Rank risk assessment for the sample based on field observations and incident assessment.
- Sample Classification: select one : Clinical, Environmental, Food, Other (specify)
- <u>Sample ID</u>: list all unique identifiers and provide sample description. Multiple samples can be listed on the same form; "See back/attached for detailed list" is acceptable
- <u>Sample Type</u>: select the most appropriate one.
- # samples: total number of samples (exclude blanks)
- # containers: total number of outer containers
- <u>Container type</u>: describe the container
 - o i.e., 5 gal. metal paint can
 - o i.e., 16 oz. plastic jar
- <u>Testing Requested</u>: mark one or more based on desired testing (if unsure, consult lab on arrival)
- <u>Includes (list number)</u>: list number of duplicates, spiked samples, spiked duplicates, and blanks
- <u>Submitter Agency</u>: list submitter's agency
- <u>Submitter Name</u>: print the submitter's name
- Submitter may be different from the collector
- Organization Address, City, State, Zip (code): physical address of submitter
- <u>Contact Person for Results</u>: person telephoned with preliminary and final results. This individual may be different from submitter or collector. Multiple names may be given.
- Additional Comments/Information: any other pertinent information provided

Field Screening Form: A Field Screening Form must be completed for each environmental and food preparedness sample submitted for testing and must accompany the Chain of Custody Form and Request for Testing Form. This document details the pre-screening performed on these samples prior to submission at DPHL. Samples not prescreened maybe refused for analysis at DPHL. Contact DPHL prior to submitting any sample to discuss these requirements.

- 1. For each environmental, food, or otherwise requested sample, complete the form fully with the exception of the gray box at the bottom of the form.
- Submitter/Tester: list both if not the same individual
- <u>Date</u>: List the date screening was performed; this may or may not be the collection or submission date.
- Location: List the place sample was collected.
- <u>Sample ID</u>: List the submitter determined number or name. A case ID or other unique identifier may be used. This ID must match the Chain of Custody and Request for Testing Form.
- <u>Sample description/identifier</u>: Description of sample to allow differentiation of this sample from any other sample or specimen.



- 2. The Results block is a horizontally drive line detailing all screening performed on the sample to determine potential hazards and information determined in during the field screening process. Detail this section as completely as possible. If assistance is needed in performing field screening, contact DPHL for assistance and referral.
- <u>Test</u>: mandatory tests are shown with a star (*) beside the test ID. All mandatory tests must be completed prior to submission when possible. If the test in unable to be performed, DPHL staff will discuss and evaluate the risk prior to acceptance. Recommended tests are shown with a double star (**) beside the test ID. For additional testing, such as HHA and Other, list the specific testing performed, such as a kit name or instrument type.
- Result: Detail the result, including units if available for all field screening performed. ALL testing fields are required except:
 - o FTIR/RAMAN strongly recommended
 - o HHA (Hand-held Assay)
 - Other
- <u>Rejection Range</u>: DPHL provides a rejection range criteria list illustrating the values and properties that can cause a sample to be refused admittance to DPHL for testing. This column is informational and does not require any entry.
- <u>Date/Time</u>: list the date and time the screening was performed.
- Equipment/Method used: provide a description of what equipment or method was used for the screening technique.
- <u>Calibration/Control passed</u>: circle one of the choices based on the screening technique used. Some methods do not have calibration or control; circle "N/A" for these methods.
- Comments: can be left blank or completed as needed.
- 3. The Cleared for Preparedness Testing block is completed with review of documentation at DPHL. Do not sign this section until instructed to do so by DPHL staff.

LIMS Test Requisition: A LIMS Test Requisition must be completed for all clinical specimens submitted for testing at DPHL. Facilities with LIMS entry access may enter the required information into LIMS PRIOR to submission of samples. Samples will not be received without a LIMS Test Requisition Form or all appropriate LIMS data entry completed prior to receipt.

- 1. One LIMS Test Requisition is required per patient. Multiple tests may be requested on the same form, but will generate multiple barcodes.
- 2. This form is used for all clinical sample submissions. Complete the form as best as possible; some fields are not mandatory for preparedness testing and are denoted below.
- 1. <u>Barcode Label Here</u>: if the specimen has been entered into LIMS, append the appropriate barcode label. A facility generated barcode containing appropriate information may also be included, but should not cover this spot.
- 2. MCI#: list patient MCI number, if known.
- 3. Submitter/Practitioner Name: enter practitioner name for organization authorizing testing.
- 4. Collection Date: list the date sample collected, if known include the collection time.
- 5. Name: list the full name of patient, do not use nicknames or shorten forms



- 6. <u>Address</u>: list the patient's full address, including any apartment number, development, or related information.
- 7. <u>Phone</u>: list the patient's contact telephone.
- <u>City</u>: list the patient's city or town of residence.
- State: enter the patient's state of residence
- Zip Code: enter the patient's zip code
- Birth date: enter the patient's birth date, include four digit year
- Race: enter the patient's race, if known
- Gender: enter the patient's gender, if known
- Partner Gender: this section can be left blank, if not requesting STD testing
- Ethnicity: enter the patient's ethnicity, if known
- <u>Visit Type</u>: this section can be left blank, if not requesting STD testing
- Reason for Test: mark Other (for non-STD related testing)
- <u>Clinician name and ID</u>: enter the clinician's name and appropriate ID
- <u>ICD-9</u>: enter ICD-9 code, if known
- Insurance status: unless the insurance status is known, mark unknown.
- <u>Test Requested</u>: mark the appropriate tests requested, more than 1 test may be marked per form or specimen source. List rule-out isolates under Hospital Requests; include the testing needed for rule-out isolates, i.e., *Brucella* ssp. or *Yersinia pestis*. The CT clinical tests shown individually. Mark all requested; patient requests may vary within the same exposure and/or incident.
- Gonorrhea/ Chlamydia DNA Amplification Questions for Youth through Age 18: leave blank unless requesting STD testing

Bacteriological Form: A Bacteriological Form is required for any SDWA sample submitted for Bacteriological Testing. A separate form exists for quantification testing or unknown contamination testing. Facilities with LIMS entry access may enter the required information into LIMS PRIOR to submission of samples. Samples will not be received without a Bacteriological Form or all appropriate LIMS data entry completed prior to receipt.

- 1. One Bacteriological Form is required per sample.
- <u>Barcode Number</u>: the LIMS barcode sticker matching the submitted sample is placed here. If not present, write in number. Ensure the number is also included on the sample container.
- <u>TEST Request</u>: choose Total Coliform Rule (TCR) compliance or Special
- <u>Collection Date</u>: enter the date the sample collected
- <u>Collection Time</u>: enter collection time in military / 24 hour time format; bacteriological samples must be received at DPHL with 30 hours of collection.
- PWSID: list public water system ID (ODW assigned)
- Supply Name: list PW supply name
- Sample Location: list the address of sampling
- AST/Operator #: list if known
- Collector's Name: list the collector's full name



- <u>Collector's Phone</u>: list the collector's contact phone number
- Collector's Fax #: list the collector's fax number
- Free Chlorine: list the free Chlorine in mg/L (ppm) as tested at collection
- Total Chlorine: list total Chlorine in mg/L (ppm) as tested at collection
- Not Chlorinated: mark only if the sample source is not chlorinated
- Sample Type: select routine, repeat, special, or replacement
- Sample Type: select type of sample
- Repeat and Replacement: list original sample barcode #
- Remarks: list any applicable remarks
- <u>Sample Point</u>: mark sample collection location
 - a. MBS: Men's Bathroom Sink
 - b. LBS: Ladies' Bathroom Sink
 - c. BS: Bathroom Sink
 - d. US: Utility Sink
 - e. HS: Hand Sink
 - f. WT: Water Tap
 - g. KS: Kitchen Sink
 - h. OT: Outside Tap
 - i. FFT: Frost-Free Tap
 - j. Other: any point that not meeting above

Chemical Form: A Chemical Form is required for any SDWA sample submitted for Chemical Testing. Facilities with LIMS entry access may enter the required information into LIMS PRIOR to submission of samples. Samples will not be received without a Chemical Form or all appropriate LIMS data entry completed prior to receipt.

- 1. One Chemical Form is required per sample. Multiple tests may be requested on the same form if compatible with each testing type. Please review the preservation, container type, and sample volume (located on the Chain of Custody) for each sample prior to submission.
- <u>Barcode Number</u>: the LIMS barcode sticker matching the submitted sample is placed here. If not present, write in number. Ensure the number is also included on the sample container.
- <u>Collection Date</u>: enter the date the sample collected
- <u>Collection Time</u>: enter collection time in military / 24 hour time format; bacteriological samples must be received at DPHL with 30 hours of collection.
- <u>TEST Request</u>: mark the type of test requested
- Confirmation and Replacement: enter original sample #
- PWSID: list public water system ID (ODW assigned)
- Supply Name: list PW supply name
- Facility Name: list facility name
- <u>Facility #</u>: list facility number
- <u>Sample Point Name</u>: list assigned name of sample point



- <u>Sample Point #</u>: list order of sampling
- AST/Operator #: list if known
- Collector's Name: list the collector's full name
- <u>Collector's Phone</u>: list the collector's contact phone number
- Collector's Fax #: list the collector's fax number
- Free Chlorine: list the free Chlorine in mg/L (ppm) as tested at collection
- <u>Total Chlorine</u>: list total Chlorine in mg/L (ppm) as tested at collection
- Not Chlorinated: mark only if the sample source is not chlorinated
- pH Field Test: list pH of sample
- Analyte Group: mark the appropriate individual test to be performed for this sample
 - a. Routine: NO₃, NO₂, Fe, Na, pH, Fl, Cl
 - b. <u>Full Chem.</u>: NO₃, NO₂, Fe, Na, pH, Fl, Cl, alkalinity (ALK), Ca hardness, Total Dissolved Solids (TDS)
 - c. Trace: As, Be, Be, Cd, Pb, Hg, Ni, Se, Sb, Tl
 - d. <u>Individual tests</u> NO₃-, Fl⁻, Cyanide (CN), Mn, Cu, Sulfate (SO₄²⁻): mark each one desired
 - e. <u>VOCs</u>: Volatile Organic Compounds
 - f. TTHM: Total TriHaloMethanes (Chlorine disinfection byproducts)
 - g. Other: list the specific test to be performed
- 2. DPHL does not currently perform pesticides, herbicides, and HHA5 (HaloAcetic Acids) testing at DPHL. These samples will be referred to a contract laboratory.

Sample Transport: Transport all documentation and specimens together.

- 1. The completed Chain of Custody form, the Request for Preparedness Testing, Field Screening Form (environmental preparedness samples only), LIMS Test Requisitions (clinical samples only), and any other supporting documentation, should be sealed tightly in its own plastic ziplock bag and attached to the exterior of the secondary container of the sample transport container.
- 2. The submitter is responsible for ensuring sample security as long as the specimen is in their custody.
- 3. When the custody of the sample is transferred, each receiver will document sample receipt and release.
- 4. Copies of the chain of custody form may be provided to submitters, the original remains with the sample.
- 5. Samples may be delivered to the laboratory using any of the following methods:
 - a. Delivery by the Submitter: Contact DPHL at 302.223.1520 prior to transport/delivery.
 - b. DPHL courier: Call 302.223.1520 to arrange pickup. Please keep in mind that using the DPHL courier may increase transport time.
 - c. Professional Carrier: FedEx, DHL, or UPS. Specify rush delivery. Use the appropriate Packing Instruction.



Sample Packaging: Correctly preserving and preparing samples for transport is critical to ensuring the integrity of the sample and the safety of those handling these samples. Steps for preparing samples for transport are as follows.

- 1. The submitter should contact the Delaware Public Health Laboratory (DPHL) at 302.223.1520 to answer any questions related to any aspect of sample collection, preservation, packaging, and/or transport.
- 2. Samples must be labeled and tightly sealed in a container (blood tube, specimen cup, etc).
- 3. Prepare specimens for air transport. Place clinical specimens in a rated secondary container (such as a rigid transport container).
- 4. Place in a transport container, preferably a cardboard box made for shipment (Class 6.2 infectious substances for clinical samples).
- 5. Fill container with bubble wrap, Styrofoam peanuts, etc. to prevent breakage of sample.
- 6. If ice or ice packs are necessary for transport, contain the ice so that leakage into specimen or out of the transport box is avoided.
- 7. Transport containers should be secured with evidence tape or a custody seal. The signature of the person sealing the evidence with the date must be written across the seal in indelible ink.
- 8. Mark on the outside of the transport container:

Send to: Delaware Public Health Laboratory Attn: Preparedness Laboratory 30 Sunnyside Road Smyrna, Delaware 19977

9. Complete any additional required paperwork. Attach chain of custody, request for testing, and any additional forms to the box according to the instructions above.

Biological Preparedness Samples: Contact DPHL Microbiology Section at 302.223.1520.

Additional Sample Packaging requirements:

1. Refer to DPHL Specimen Collection Guidelines for Bioterrorism Samples.

Chemical Preparedness Samples: Contact DPHL Chemical Preparedness Section at 302.223.1520.

Additional Sample Packaging requirements:

- 1. Refer to DPHL Specimen Collection Guidelines for Chemical Exposure Samples.
- 2. Clinical chemical exposure sample collection must follow CDC's "Chemical Exposure Event Specimen Collection".
- 3. Follow packaging guidelines for clinical samples provided in the CDC document "Shipping Instructions for Specimens Collected from People Potentially Exposed to Chemical Agents".
- 4. Samples must be labeled and tightly sealed in a container (rated jar, blood tube, specimen cup, etc.).
 - a. Follow Packing Instruction 650 (Biological Substance Category B) for clinical samples.
 - b. Environmental samples must *minimally* be triple layer packaged with the exterior decontaminated. Utilize drinking water sampling bottles for large volume samples.



- 5. The initials of the person sealing the evidence and the date must be across the seal of a minimum of two layers of packaging in indelible ink.
- 6. Closure points (tube or cup, bags, boxes, containers, etc.) must be sealed with evidence tape with the collector's initials and date of collection written half on and half off the tape.
 - a. Place in a transport container, preferably a cardboard box made for shipment (clinical specimens must comply with Packing Instruction 650).
 - b. Fill container with enough sorbent to prevent breakage of sample. Contain ice packs or dry ice so that leakage into specimen or out of the transport box is avoided.
 - c. Urine samples must be frozen or freeze in shipment, dry ice is recommended.
 - d. Blood tubes must NOT freeze, but be chilled, ice packs are recommended.
 - e. Blood and urine must be packaged and shipped separately.
- 7. Follow Packing Instruction 954 if using dry ice.
- 8. If directed to ship clinical samples to CDC:
 - d. Contact DPHL for further directions and shipping address.
 - e. Follow guidelines provided in the CDC document "Shipping Instructions for Specimens Collected from People Potentially Exposed to Chemical Terrorism Agents".
- 9. If directed to ship environmental samples to a network or affiliate laboratory:
 - a. Contact DPHL for further directions and shipping address.
 - b. Follow guidelines provided in IATA's Dangerous Goods Regulations, Section 3.11 "Transporting Samples for Further Testing" and US DOT 49 CFR 173.156 "Exceptions for ORM Materials".

Revised 04/09/12 tl